



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive B MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-2803

June 14, 2019

Re: Animal Welfare Assurance
A3609-01 [OLAW Case M]

Dr. Peter Dorhout
Vice President for Research
Kansas State University
(b) (4) Anderson Hall
Manhattan, KS 66506-0113

Dear Dr. Dorhout,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 13, 2019 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Kansas State University, following up on an initial telephone report on May 17, 2019. According to the information provided, OLAW understands that the lights in a rodent facility had been on continuously for nearly one month. Due to interference with the study, 82 rats were euthanized, and the data were discarded.

The corrective actions consisted of installing a new lighting control module and having the automated building management light control system alert key staff via email or text if lights do not go on or off. An override switch was also installed to allow lights to be turned on or off manually if the control fails.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and reduce the likelihood of a recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. We recommend contacting the NIH funding component regarding the loss of animals and data. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

June 13, 2019

Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982
Phone: 301-594-2061
FAX: 301-402-2803
E-mail: olawdco@mail.nih.gov

Dear Dr. Morse:

Kansas State University, in accordance with Assurance A3609-01 and PHS Policy IV.F.3.b., provides this report of deviation from the provisions of the Guide regarding an incident of a failed lighting control system resulting in lights being on 24 hours straight in a small rodent satellite facility. Contact was made to the OLAW office on 05/15/2109, 05/16/2019 and on 05/17/2019 an individual was reached. This incident was first reported to Dr. Axel Wolff, OLAW, on May 17, 2019 via a telephone call by the K-State IACUC chair and two other IACUC members.

On the morning of May 8, 2019, researchers discovered that the 12:12 light cycle in a small rodent satellite facility had malfunctioned and the lights had been on for 24 hours straight. Upon further research, it was discovered the lighting control module (AccuControl) had failed, and the default to the system failure was for lights to stay on. Through pulling data from a photodiode, that is part of a running wheel system, which can log data between light/dark cycles, it appears that the lights had been on continuously since April 12th, 2019.

We held an emergency meeting with the Institutional Official (Vice President for Research), the Attending Veterinarian, the Associate Vice President for Research, the Associate Dean for Research, and the two affected Principal Investigators the afternoon of May 8, 2019. It was determined at this time that the affected animals (82 combined total rats) could not be used in future studies, and any data collected would have to be thrown out. No overt clinical indicators of pain/distress were observed. On May 9, 2019, the rats were humanely euthanized.

NIH Grant 1R01HL142877-01 and 1R15HL137156-01A1 were associated with this incident.

Plan and schedule for correction and prevention:

The installation of a new lighting control module is expected to be completed by the end of the month of June, 2019. These additional safeguards will also be put in place:

1. The automated building management light control system is being programed to automatically send email & text "Alerts/Notifications" to the Attending Veterinarian, CMG Office, and KSU Facilities in the event the lighting controls fail to turn lights ON/OFF as programed. The automated building management light control system's trend tracking feature has been activated so that light cycles can be checked daily to verify that lights are turning ON/OFF as programed. A manual override switch is being installed so that lights can be manually controlled (*i.e.*, turned ON/OFF) if the automatic lighting controls fail in the future.

At their meeting on June 6, 2019, the IACUC committee reviewed and accepted the correction and prevention plan as submitted.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Peter K. Dorhout, PhD
Vice President for Research/Institutional Official
Kansas State University

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, June 14, 2019 9:24 AM
To: URCO comply
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Noncompliance Report

Thank you for this report. We will send a response shortly.

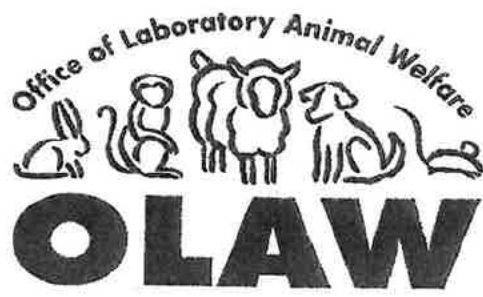
Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: URCO comply <comply@ksu.edu>
Sent: Thursday, June 13, 2019 4:37 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Final Noncompliance Report

Dr. Morse,

Please find attached the final noncompliance report in regards to the preliminary report conducted, via telephone, on May 17, 2019 with Dr. Axel Wolff.

Respectfully,
Kansas State University
University Research Compliance Office (URCO)



Initial Report of Noncompliance

By: aw

Date: 5/17/19

Time: 9:45

Name of Person reporting: McKen Traub, DVM, MS, DACVP, Vet
Telephone #: (b)(6)
Fax #: [redacted]
Email: [redacted]

Name of Institution: Kansas State U
Assurance number: A3609

Did incident involve PHS funded activity? Yes
Funding component: _____
Was funding component contacted (if necessary): _____

What happened?
For 27 days lights stayed on in the rat room satellite facility. Caused problems with study so needed to euthanize the rats.
Species involved: Rat
Personnel involved: _____
Dates and times: _____
Animal deaths: 82

Projected plan and schedule for correction/prevention (if known): _____
Put in better light timers, sensors, have people check rooms at night.

Projected submission to OLAW of final report from Institutional Official: _____

OFFICE USE ONLY
Case # _____